REMARKS

This paper is responsive to an *Official Action* that issued in this case on September 17, 2007. In that *Action*, the Examiner rejected pending claims 1-17 and 19-36 under 35 USC §102 as being anticipated by U.S. Pat. No. 6,470,302 to Cunningham *et. al.* Claims 18 and 37 were rejected under 35 USC §103 as being obvious over the combination of Cunningham and WO 03/096307 to Lacey.

Applicant amends claims 5, 24 and 34, to more particularly point out and distinctly claim the present invention. Applicant also cancels claim 37 and adds new claim 38. Reconsideration is respectfully requested based on the foregoing amendments and the following comments.

Rejection of Claim 1
Under 35 USC §102

> An apparatus comprising a receiver, wherein:
> said receiver has at least three degrees of freedom, wherein axes of said three degrees of freedom intersect; and
> said receiver receives an end effector, wherein said end effector removably couples to said receiver.

In Cunningham, axes of three degrees of freedom DO NOT intersect. The Examiner alleges that Cunningham discloses an apparatus comprising a receiver having at least three degrees of freedom (translation, pitch & yaw), wherein axes of said three degrees of freedom intersect. The Examiner cites to claim 5 of Cunningham to support the allegation that the three axes intersect.

The language of claim 5 does not recite that the axes of three degrees-of-freedom intersect. Rather, the language of claim 5 recites that "axes of at least two of said degrees of freedom intersect and at least one axis of another of said degrees of freedom is offset from said intersection."

Applicant agrees that Cunningham discloses a sensing assembly (which corresponds most nearly to "catheter unit assembly 34" as defined at col. 7, lines 36-41). The sensing assembly has three degrees of freedom. In fact, the axes of the degrees of freedom of the catheter unit assembly are:

- a translational axis coincident with the long dimension of shaft 44 (translational degree of freedom);

- a pitch axis running through bearing 42 (rotational degree of freedom); and
- a yaw axis running through bearing 58 (rotational degree of freedom).

(*See* Figure 4 of Cunningham.)

It is clear that there is an offset between the translational axis and the intersection of the yaw and pitch axes, such that the axes of the three degrees of freedom DO NOT intersect. This offset is roughly equal to the radius of bearing 42.

The problematic nature of this offset was discussed in the Background section of applicant's specification at para. 0007. The fact is, developing a design in which all three of these axes intersect was challenging and represents a significant advance over the Cunningham device.

Claim 1 is therefore allowable over Cunningham. It is therefore requested that the Section 102 rejection of claim 1, and claims 2-9 dependent thereon, be withdrawn.

Rejection of Claim 10
Under 35 USC §102

Claim 10 recites and apparatus comprising:

> an end effector; and
> a movable member, wherein:
> said end effector reversibly couples to said movable member to simulate a vascular access procedure; and
> said movable member moves along a linear path in response to manipulation of said end effector.

The Examiner alleges that Cunningham discloses:

> an end effector (catheter 47); and a movable member (friction wheels 84 & 85 and/or anchor pulleys), wherein: said end effector reversibly couples to said movable member to simulate a vascular access procedure ...; and said movable member moves along a linear path in response to manipulation of said end effector (FIG. 5B & the associated text).

1. The whole "catheter needle assembly (47)" is NOT an end effector. Catheter needle assembly consists of both needle assembly (68) and catheter hub (46). The catheter hub is connected to catheter (91). As implemented in Cunningham, neither the catheter hub (46) nor the catheter (91) are "end effectors." The catheter (91) is

non-movable and hub (46), although rotatable (about bearing (90)), is not properly characterized as a "device, tool, or instrument for performing a task."

Rather, in the embodiment that is depicted in FIG. 5A, the "end effector" is the needle assembly (68). The needle assembly is the "instrument" that is actually manipulated to effect the simulated "vascular access." In the embodiment that is depicted in FIG. 5B, there are arguably two end effectors: needle assembly (68) and/or wire (49).

2. Friction wheels (84) and (85) of the embodiment in FIG. 5B are indeed "movable members." Friction wheel (85), in conjunction with encoder disk (82) and encoder sensor (81), measures translational movement of needle shaft (72). Friction wheel (84), in conjunction with encoder disk (86) and encoder sensor (88), measures translational movement of wire (49).

   It is quite clear, however, that the friction wheels DO NOT move along a linear path in response to manipulation of said end effector. As is evident from the Figures and made explicit in the text, the friction wheels *rotate*, they do not move in a linear path.

To be clear, the structure/arrangement that is being claimed in claim 10 is shown, for example, in FIGs. 11C and 11D of applicants' drawings. The "movable member" is referenced by call out "972." These Figures depict the "end effector" (needle 650 or catheter 758) coupling to the movable member 972. As the needle/catheter is "inserted" further (into a patient), the movable member moves along axis 1-1 in linear fashion. The structural arrangement of this aspect of applicants' device is quite different from the relevant structure of Cunningham's device.

Claim 10 is therefore allowable over Cunningham. It is therefore requested that the Section 102 rejection of claim 10, and claims 11-18 dependent thereon, be withdrawn.

Claim 19 recites:

> An apparatus comprising a receiver for an end effector, wherein said receiver comprises:
> a frame;
> an arrangement for providing two orthogonal axes of rotation for said frame, wherein said frame is coupled to said arrangement; and
> a movable member, wherein:
> said movable member receives an end effector during a vascular access procedure;
> said movable member moves along a linear path in a region defined by said frame; and
> said linear path intersects said two orthogonal axes of rotation of said frame.

Claim 19 incorporates aspects of independent claims 1 and 12. In particular, it recites limitations pertaining to the axes of motion and limitations pertaining to the movable member.

The Examiner's attention is directed to FIGs. 10A-10C and 11. FIG. 11 depicts frame (1149), which comprises lower plate (1150) and upper plate (1152). (*See*, para. [0088].)

In the illustrative embodiment that is depicted in FIG. 10A, the "arrangement for providing two orthogonal axes of rotation for said frame" is the base and gimbal assembly (1078). These two orthogonal axes of rotation are identified as axis "2-2" and axis "3-3." Movable member (972) has already been discussed in conjunction with claim 11. The "linear path" is is along axis "1-1." It can be seen in FIG. 10A that the two orthogonal axes and the linear path intersect.

As previously discussed, Cunningham does not disclose what is recited in claim 19. The Examiner construes the "movable member" to be friction wheels (84) or (85) – they do not move along a linear path – they rotate.

But even if shaft (44) were to be construed as the "movable member," its three axes of movement (translation, yaw, and pitch) do not intersect. In particular, although the translational axis intersects the "yaw" axis (*i.e.*, the axis running "vertically" through

bearing (58)), it does NOT intersect the "pitch" axis (*i.e.*, the axis running "horizontally" through bearing (42)).

Claim 19 is therefore allowable over Cunningham. It is therefore requested that the Section 102 rejection of claim 19, and claims 20-23 dependent thereon, be withdrawn.

Rejection of Claim 24
Under 35 USC §102

Amended claim 24 recites an apparatus comprising:

> pseudo skin; and
> a receiver for coupling to an end effector, wherein:
> said receiver is disposed beneath and at least partially covered by said pseudo skin; and
> said receiver has no offset degrees of freedom.

The "receiver" recited in claim 24 is depicted in FIG. 10A as "receiving module (1076)." It has three degrees of freedom (translation about axis 1-1, yaw about axis 3-3, and pitch about axis 2-2). None of these degrees of freedom are offset from one another.

The structure in Cunningham that is most analogous to the claimed "receiver" is, in fact, catheter unit assembly (34). As already discussed, catheter unit assembly (34) does have an "offset degree[s] of freedom."

To put an end to any further discussion on what the proper interpretation of "disposed beneath" means, applicants amends claim 24 to recite that the receiver is "disposed beneath *and at least partially covered by*" said pseudo skin. At least some of pseudo skin **220** that is stretched across openings **330** and **332** in housing **216** "at least partially cover[s]" the receiver. (*See*, *e.g.*, FIGs. 3, 4A and para. [0051])

It is clear from FIGs. 3 and 7 of Cunningham that the "pseudo skin" of Cunningham (*i.e.*, belt 108) does not "partially cover" the element that the Examiner considers to be the "receiver" (*i.e.*, shaft (44)).

Claim 24 is therefore allowable over Cunningham. It is therefore requested that the Section 102 rejection of claim 24, and claims 25-33 dependent thereon, be withdrawn.

Amended claim 34 recites an apparatus comprising:

> pseudo skin; and
> a receiver for coupling to an end effector, wherein:
> said receiver is disposed beneath and at least partially covered by said pseudo skin; and
> said receiver comprises a force-feedback assembly.

As discussed above, Cunningham does not disclose that the receiver is "disposed beneath and at least partially covered by said pseudo skin."

The Examiner considers the "receiver" to be "shaft (44)." Although Cunningham's device as a whole does include a force-feedback assembly, shaft (44) most certainly does not include a force-feedback assembly.

Cunningham's force-feedback unit (54) can be seen in FIG. 4 and in more detail in FIG. 6. Clearly, it is not a part of shaft (44). As previously noted, catheter unit assembly (34) is a better analogue for the claimed "receiver." But, regardless of which feature in Cunningham is properly construed as the "receiver," it is clear that this feature is not "disposed beneath and at least partially covered by said pseudo skin."

Claim 34 is therefore allowable over Cunningham. It is therefore requested that the Section 102 rejection of claim 34, and claims 35-36 dependent thereon, be withdrawn.

New claim 38 recites:

> An apparatus for simulating a vascular access procedure, said apparatus comprising a receiver, wherein:
> said receiver receives an end effector, wherein said end effector removably couples to said receiver during simulation of said vascular access procedure;
> said receiver has plural degrees of freedom; and
> axes of all of said plural degrees of freedom of said receiver intersect one another.

Cunningham does not disclose what is recited in claim 38. As previously discussed, in Cunningham, neither shaft (44) nor any other structure that the Examiner might identify as appropriately identify as "a receiver" has plural degrees of freedom wherein axes of all of such plural degrees of freedom intersect one another. As a consequence, claim 38 is allowable over Cunningham.

Conclusion

It is believed that claims 1-36 and 38 now presented for examination are in condition for allowance. A notice to that effect is solicited.

Respectfully,
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